

REMARKS

Specification

The Specification has been amended as requested in the Office Action.

Double Patenting Objection

Terminal Disclaimers are enclosed to address the double patenting rejections.

Claims

a. Claim Objections

Claims 21 and 43 have been amended as suggested in the Office Action.

b. Section 101 Rejection

The claims have been amended to address the Section 101 objections. Applicant appreciates the Examiner's suggestion of language to overcome the objections.

c. Section 103 Rejections

The claims have been rejected as unpatentable over Edwards in view of Mulier, or Edwards in view of Mulier and Roskos.

Independent claim 43 has been amended to specify that the microspheres of this invention are entirely biodegradable, unlike the metal microspheres of Edwards. As the Office Action notes, Edwards does not teach entirely biodegradable microspheres.

The Office Action notes that "[t]he Examiner does not believe the specification of the instant invention, as originally filed, supports any type of microsphere that is entirely or completely biodegradable." Applicant strongly disagrees. The original specification at page 9, lines 6-21, discusses a biodegradable microsphere that is gradually absorbed or disintegrated. Moreover, "biodegradable" means "capable of being decomposed by natural biological

processes.” Webster’s II New Riverside University Dictionary at 174 (Borton 1984) (attached).

When something is biodegradable, it is “completely” biodegradable. If it is not “completely” biodegradable, the term is modified by saying that the material is “partially biodegradable”.

Thus, Applicant’s specification as filed supports that the microspheres are “entirely biodegradable”. As the Office Action notes, this distinguishes over Edwards, which teaches “tiny hollow metallic spheres with a large number of pores formed therein so that the therapeutic substance can be released through the pores.” Edwards, col. 16, lines 35-38. The metal spheres can be coated with a biodegradable coating (id. at lines 47-48), but the spheres are not biodegradable. As Applicant noted in the previous Office Action response, the entirely biodegradable microspheres of Applicant’s invention are a significant improvement not taught or suggested by the cited art. Moreover, the term “biodegradable” interpreted in its common meaning means “entirely biodegradable.” Thus, the specification as filed supports this claim limitation.

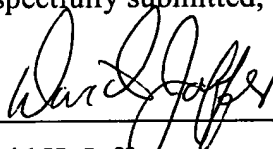
CONCLUSION

Applicant has amended the Specification to correct the error noted in the Office Action and provided Terminal Disclaimers to address the double patenting rejections. Applicant has also amended the claims to address the rejections under Sections 101 and 103. For the reasons discussed above, Applicant believes the claims as now presented distinguish the present invention from the cited prior art, and that these claims are now in condition for allowance.

If any further questions should arise prior to a Notice of Allowance, the Examiner is invited to contact the attorney at the number set forth below.

Date: August 4, 2006

Respectfully submitted,



David H. Jaffer

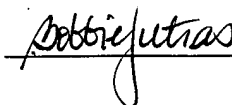
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Sign

binding force • biosynthesis

nucleus. 2. The work required to remove an atomic electron to an infinitely remote position from its orbit.

binding force *n.* A strong interaction.

bin-dle-stiff (bīn'dl-stīf') *n.* [E. *bundle*, alteration of BUNDLE + STIFF.] Slang. A hobo or migrant worker.

bind-weed (bīnd'wēd') *n.* 1. Any of several trailing or twining plants of the genus *Convolvulus*, with pink or white trumpet-shaped flowers. 2. Any of various plants similar to a bindweed.

bine (bīn) *n.* [Dial. of *bind*.] 1. The flexible stem of a climbing or twining plant, as the hop, woodbine, or bindweed. 2. A plant whose stem is a bine.

Binet age (bī-nā') *n.* A person's mental age as determined by the Binet-Simon scale.

Binet-Simon scale (bī-nā'sē-mōn', -sī'mon) *n.* [After Alfred Binet (1857-1911) and Théodore Simon (1873-1961).] Any of a series of early psychological tests of childhood intelligence.

binge (bīnj) [Dial. *binge*, to soak.] Slang. —*n.* 1. A drunken spree. 2. A period of uncontrolled self-indulgence <an eating binge> —*vi.* **binged, binging, binges.** To be uncontrolled and self-indulgent.

bingo (bīngō) *n., pl. -gos.* [Orig. unknown.] A game of chance in which players put markers on a pattern of numbered squares according to numbers drawn and announced by a caller.

bin-na-ble (bīn'ā-kāl) *n.* [Alteration of ME *bitakil* < OSp. *bitacula* or OPort. *bitacula* < Lat. *habitaculum*, habitation < *habitare*, to inhabit.] The nonmagnetic stand which supports a ship's compass case.

bin-oc-u-lar (bī-nōk'yə-lər, bī-) *adj.* 1. Relating to, used by, or involving both eyes simultaneously. 2. Having two eyes arranged to produce stereoscopic vision. —*n.* often **binoculars.** An optical device, esp. a pair of field glasses, designed for use by both eyes simultaneously. —**bin-oc-u-lar-i-ty** (-lār'ī-tē) *n.* —**bin-oc-u-lar-ly** *adv.*

bin-om-i-al (bī-nō'mē-əl) *adj.* [*<* NLat. *binomius*: Bī + Gk. *nomos*, part.] Composed of or relating to two names or terms. —*n.* 1. Math. An expression composed of two terms joined by a plus or minus sign. 2. Biol. A taxonomic name. —**bin-om-i-al-ly** *adv.*

binomial distribution *n.* The frequency distribution of the probability of a specified number of successes in an arbitrary number of repeated independent Bernoulli trials.

binomial nomenclature *n.* A system of classifying plants and animals by a double name, the first being the name of the genus and the second that of the species.

binomial theorem *n.* A mathematical theorem that specifies the expansion of a binomial to any power without requiring the explicit multiplication of the binomial terms.

bi-nu-cle-ate (bī-nō'klē-īt, -ār, -nyōō') *also* **bi-nu-cle-ated** (-ā'tīd) *adj.* Having two nuclei.

bio- or **bi-** *pref.* [Gk. < *bios*, life.] 1. A life <biolysis> 2. Living organism <biome> 3. Biology; biological <biophysics>

bi-o-ac-tiv-i-ty (bī'ō-āk-tiv'ī-tē) *n.* The effect of a given agent, as a vaccine, on a living organism.

bi-o-as-say (bī'ō-ās'ā, -ā-sā') *n.* Evaluation of a drug by comparison of its effect with that of a standard on a test organism.

bi-o-as-tro-nau-tics (bī'ō-ās'trō-nō'tīks) *n. (sing. in number).* Study of the medical and biological effects of space flight.

bi-o-a-vail-a-bil-i-ty (bī'ō-ā-vā'lō-bil'ī-tē) *n.* The degree to which an agent, as a nutrient or drug, becomes available at the physiological site of activity.

bi-o-cat-a-lyst (bī'ō-kāt'līst) *n.* A substance that modifies and initiates the rate of a biological process. —**bi-o-cat-a-lyt-ic** (-ī'tīk) *adj.*

bi-o-cen-ol-ogy (bī'ō-sē-nō'lō-jē) *n.* Ecol. Study of communities and member interactions in nature.

biochemical oxygen demand *n.* The amount of dissolved oxygen needed to meet the metabolic requirements of microorganisms in a water environment rich in organic matter, as sewage.

bi-o-chem-is-try (bī'ō-kēm'ī-strē) *n.* The chemistry of biological processes and substances. —**bi-o-chem-i-cal** (-ī-kāl) *adj.* —**bi-o-chem-i-cal-ly** *adv.* —**bi-o-chem'ist** *n.*

bi-o-cide (bī'ō-sīd') *n.* A substance, as an antibiotic or pesticide, capable of destroying living organisms. —**bi-o-cid-al** (-sīd'ī) *adj.*

bi-o-cli-mat-ol-ogy (bī'ō-klī'mā-tō'lō-jē) *n.* Study of the effects of climate on organic life. —**bi-o-cli-mat-ic** (-klī-māt'īk) *adj.*

bi-o-de-grad-a-ble (bī'ō-dī-grā'dā-bal) *adj.* Capable of being decomposed by natural biological processes.

bi-o-eth-ics (bī'ō-ēth'īks) *n. (sing. or pl. in number).* Study of the moral and ethical questions involved in applying new biological and medical findings, as in genetic engineering, neurobiology, and drug research. —**bi-o-eth-ic** *adj.* —**bi-o-eth-i-cist** (-ī-sīst) *n.*

bi-o-feed-back (bī'ō-fēd'bāk') *n.* A technique in which an attempt is made to consciously control a bodily function believed to be involuntary, as heartbeat or blood pressure, by using an instrument to monitor the function and to signal changes in it.

bi-o-fla-von-oid (bī'ō-flā'vō-nōid') *n.* Any of a group of biologically active substances widely found in plants and functioning in the maintenance of the walls of small blood vessels.

bi-o-gas (bī'ō-gās') *n.* A mixture of carbon dioxide and methane produced through bacterial action.

bi-o-gen-e-sis (bī'ō-jēn'ī-sīs) *also* **bi-o-gen-y** (bī-ō-jē-nē) *n.* 1. The doctrine that living organisms develop only from other living

organisms and not from nonliving matter. 2. Generation of living organisms from other living organisms. —**bi-o-gen-et-ic** (-jē-nēt'īk), **bi-o-gen-et-ical** *adj.* —**bi-o-gen-et-ic-al-ly** *adv.*

bi-o-ge-o-gra-phy (bī'ō-jē-ō-grā-fē) *n.* Biological study of the geographic distribution of animals and plants. —**bi-o-ge-o-graph-ic** (-jē-ō-grāf'īk), **bi-o-ge-o-graph-i-cal** *adj.*

bi-o-gra-pher (bī'ō-grā-fər, bē-) *n.* A writer of a biography.

bi-o-graph-i-cal (bī'ō-grāf'ī-kāl) *also* **bi-o-graph-ic** (-grāf'īk) *adj.* 1. Containing, composed of, or relating to the facts or events in a person's life. 2. Of or relating to biography as a literary form. —**bi-o-graph-i-cal-ly** *adv.*

bi-o-gra-phy (bī'ō-grā-fē, bē-) *n., pl. -phies.* [Med. Gk. *biographia*: *bios*, life + *graphia*, -graphy.] 1. A written account of a person's life. 2. Biographies as a whole.

bi-o-haz-ard (bī'ō-hāz'ərd) *n.* A biological material, esp. if infective, that poses a threat to humans or their environment.

bi-o-in-stru-men-ta-tion (bī'ō-in-strā-mén-tā'shən) *n.* 1. Use of instruments for recording or transmitting physiological data. 2. Instruments used in bioinstrumentation.

bi-o-log-i-cal (bī'ō-lōj'ī-kāl) *also* **bi-o-log-ic** (-lōj'īk) *adj.* 1. Of or relating to biology. 2. Of, relating to, caused by, or affecting life or living organisms. —*n.* **biologic.** A drug derived from a biological source. —**bi-o-log-i-cal-ly** *adv.*

biological clock *n.* An intrinsic biological mechanism responsible for the periodicity or other time-dependent aspects of certain classes of behavior in living organisms.

biological half-life *n.* HALF-LIFE 2a.

biological warfare *n.* Warfare in which disease-producing microorganisms or organic biocides are used to destroy human life, livestock, or crops.

bi-o-log-y (bī'ō-lō-jē) *n.* [G. *Biologie*: Gk. *bios*, life + Gk. *logos*, reckoning.] 1. The science of living organisms and life processes, including the study of structure, functioning, growth, origin, evolution, and distribution of living organisms. 2. The life processes or characteristic phenomena of a group or category of living organisms. 3. The animal and plant life of a region or place. —**bi-o-log-ist** *n.*

bi-o-lu-mi-nesc-ence (bī'ō-lōō'mā-nēs'ēns) *n.* Emission of visible light by living organisms such as the firefly and various fish, fungi, and bacteria. —**bi-o-lu-mi-nes-cent** *adj.*

bi-ol-y-sis (bī'ō-lī-sīs) *n.* Death caused or accompanied by lysis.

—**bi-ol-yt-ic** (bī'ō-līt'īk) *adj.*

bi-o-mass (bī'ō-mās') *n.* The total mass of living matter within a given volume of environment.

bi-ome (bī'ōm') *n.* An entire community of living organisms in a single major ecological region.

bi-o-med-i-cine (bī'ō-mēd'ī-sīn) *n.* 1. The branch of medicine concerned with human survival and functioning in abnormally stressful environments and with the medical aspects of protective modification of those environments. 2. The study of medicine as it relates to all biological systems. —**bi-o-med-i-cal** *adj.*

bi-o-met-rics (bī'ō-mēt'rīks) *n. (sing. in number).* The statistical study of biological data. —**bi-o-met-ric**, **bi-o-met-ri-cal** *adj.* —**bi-o-met-ri-cal-ly** *adv.*

bi-om-e-try (bī'ōm'ī-trē) *n.* Biometrics.

bi-on-ic (bī'ōn'īk) *adj.* [BIO- + (ELECTR)ONIC.] 1. Consisting of or enhanced by or as if by electronic or mechanical devices or components. 2. Of or relating to bionics.

bi-on-ics (bī'ōn'īks) *n.* [BIO- + (ELECTR)ONICS.] (*sing. in number*). Application of biological principles to the design and study of engineering systems, esp. electronic systems.

bi-o-nom-ics (bī'ō-nōm'īks) *n.* [*<* Fr. *bionomique*, pertaining to ecology < *bionomie*, ecology: Gk. *bios*, life + Gk. *nomos*, law.] (*sing. in number*). Ecology. —**bi-o-nom-ic**, **bi-o-nom-i-cal** *adj.* —**bi-o-nom-i-cal-ly** *adv.*

bi-ont (bī'ōnt') *n.* A living organism. —**bi-on'tic** (bī'ōn'tīk) *adj.*

bi-o-phys-ics (bī'ō-fīz'īks) *n. (sing. in number).* The physics of biological processes. —**bi-o-phys-i-cal** *adj.* —**bi-o-phys-i-cal-ly** *adv.* —**bi-o-phys-i-cist** *n.*

bi-o-plasm (bī'ō-plāz'm) *n.* Living protoplasm.

bi-op-sy (bī'ōp'sē) *n., pl. -sies.* The study of tissue taken from a living organism, esp. in examination for the presence of disease. —**bi-op-sic** (bī'ōp'sīk) *adj.*

bi-o-rhyth-m (bī'ō-rīth'm) *n.* 1. An intrinsically patterned cyclical biological function or process. 2. The determining factor in a biorhythm. —**bi-o-rhyth-mic**, **bi-o-rhyth-mi-cal** *adj.*

bi-o-science (bī'ō-sī'ēns) *n.* Life science.

bi-os-co-py (bī'ōs-kō-pē) *n., pl. -pies.* Medical examination of a body to determine whether it is dead.

-bi-osis *suff.* [NLat. < Gk. *biōsis*, way of life < *biōn*, to live < *bios*, life.] A way of living <parabiosis>

bi-o-sphere (bī'ō-sfēr') *n.* The part of the earth and its atmosphere in which living things exist.

bi-o-syn-the-sis (bī'ō-sīn'thī-sīs) *n.* Production of complex sub-

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